



1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Policy and Operations

4 (Emergency Amendment Amended After Comments)

5 907 KAR 23:020E. Reimbursement for outpatient drugs.

6 RELATES TO: KRS 205.5510 to 205.5520, 205.560, 205.561, 205.5631, 205.5632,  
7 205.5634, 205.5636, 205.5638, 205.5639, 205.6316(4), 217.015, 42 C.F.R. 440.120, 447.500 -  
8 447.520, 42 U.S.C. 256b, 1396a - 1396d, 1396r-8

9 STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560,  
10 205.561(2), 205.6316(4), 42 U.S.C. 1396a(a)(30), 42 U.S.C. 1396r-8

11 NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Ser-  
12 vices, Department for Medicaid Services has responsibility to administer the Medicaid Program.  
13 KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any re-  
14 quirement that may be imposed or opportunity presented by federal law to qualify for federal  
15 Medicaid funds. KRS 205.561(2) and 205.6316(4) require the department to promulgate an ad-  
16 ministrative regulation to establish the professional dispensing fee for covered drugs. This ad-  
17 ministrative regulation establishes the Medicaid Program reimbursement requirements, including  
18 the professional dispensing fee, for covered outpatient drugs dispensed to all enrolled Medicaid  
19 recipients [~~who are not enrolled with a managed care organization~~].

20 Section 1. Reimbursement. Reimbursement to a pharmacy or medical provider participating in  
21 the Medicaid Program for a covered outpatient drug provided to an eligible recipient shall be de-

1 terminated in accordance with the requirements established in this section. (1) A rebate agreement  
2 in accordance with 42 U.S.C. 1396r-8(a) shall be signed by the drug manufacturer, or the drug  
3 shall be provided based on an exemption from the rebate requirement established by 907 KAR  
4 23:010, Section 5(3).

5 (2) A pharmacy claim shall meet the point of sale (POS) requirements for services in accord-  
6 ance with 907 KAR 1:673.

7 (3) Reimbursement shall not be made for more than one (1) prescription to the same recipient  
8 during the same time period for a drug with the same:

9 (a) National Drug Code (NDC); or

10 (b) Drug or active ingredient name, strength, and dosage form.

11 (4) A timely claim payment shall be processed in accordance with 42 C.F.R. 447.45.

12 (a) In accordance with 42 C.F.R. 447.45, a claim shall be submitted to the department within  
13 twelve (12) months of the date of service.

14 (b) The department shall not reimburse for a claim submitted to the department after twelve  
15 (12) months from the date of service unless the claim is for a drug dispensed to an individual  
16 who was retroactively determined to be eligible for Medicaid.

17 (c) The department shall not reimburse a claim for a drug dispensed to an individual who was  
18 retroactively determined to be eligible for Medicaid after 365 days have lapsed from the date that  
19 the department issued the notice of retroactive eligibility.

20 (5) Reimbursement shall be denied if:

21 (a) The recipient is ineligible on the date of service;

22 (b) The drug is excluded from coverage in accordance with 907 KAR 23:010; or

23 (c) Prior authorization is required by the department and the request for prior authorization

has not been approved prior to dispensing the drug, except in an emergency supply situation.

(6) Pursuant to KRS 205.622, prior to billing the department, a provider shall submit a bill to a third party payer if the provider has knowledge that the third party payer may be liable for payment.

(a) If a provider is aware that a Medicaid recipient has additional insurance or if a recipient indicates in any manner that the recipient has additional insurance, the provider shall submit a bill to the third party in accordance with KRS 205.622.

(b) A provider who is aware that a recipient may have other insurance, but the other insurance is not identified on the medical assistance identification card or by the recipient, shall notify the department's fiscal agent of the potential third-party liability.

(7) There shall be no copayment or cost-sharing for an outpatient drug~~[Drug copayment requirements and provisions shall be as established in 907 KAR 1:604].~~

(8) If a payment is made for a drug that was not administered or dispensed in accordance with 907 KAR 23:010 or the payment was not appropriately reimbursed as required by this administrative regulation, the provider shall refund the amount of the payment to the department or the department may, at its discretion, recoup the amount of the payment.

(9) Adherence to the requirements established in this section shall be monitored through an on-site audit, post payment review of the claim, a computer audit, or an edit of the claim.

Section 2. Reimbursement Methodology. (1) Drug cost shall be determined in the pharmacy program using drug pricing and coding information obtained from nationally recognized comprehensive drug data files with pricing based on the actual package size utilized.

(2) Lowest of Logic. Except as provided in Section 4 of this administrative regulation, covered outpatient drug cost shall be reimbursed at the lowest of the:

(a) National Average Drug Acquisition Cost or NADAC, plus the professional dispensing fee;

(b) Wholesale acquisition cost or WAC, plus the professional dispensing fee;

(c) Federal upper limit or FUL, plus the professional dispensing fee;

(d) Maximum allowable cost or MAC, plus the professional dispensing fee; or

(e) The provider's usual and customary charge to the public, as identified by the claim charge[, ~~plus the professional dispensing fee~~][price].

(3) A clotting factor shall be reimbursed via the lowest of logic established in subsection (2) of this section and shall include the Average Sales Price plus six (6) percent, plus the professional dispensing fee.

(4) Pursuant to KRS 205.5510 to 205.5520:

(a) Reimbursement methodologies for the managed care population shall be subject to the terms of the awarded contract to administer the single pharmacy benefits manager or PBM for the managed care population.

(b) The single PBM for the managed care population shall not discriminate against 340B contract pharmacies via any reimbursement methodologies utilized. Section 3. Professional Dispensing Fee. (1) Effective April 1, 2017, the professional dispensing fee for a covered outpatient drug prescribed by an authorized prescriber and dispensed by a participating pharmacy provider in accordance with 907 KAR 23:010, and pursuant to a valid prescription shall be \$10.64 per pharmacy provider per recipient per drug per month.

(2) The professional dispensing fee for a compounded drug shall be \$10.64 per pharmacy provider per recipient per drug reimbursed up to three (3) times every thirteen (13) days.

Section 4. Reimbursement Limitations. (1) Emergency supply. Dispensing of an emergency supply of a drug shall be made outside of the prescriber's normal business hours and as permitted

in accordance with 907 KAR 23:010.

(2) Partial fill. If the dispensing of a drug results in partial filling of the quantity prescribed, including an emergency supply, reimbursement for the drug ingredient cost for the actual quantity dispensed in the partial fill and the completion fill for the remainder of the prescribed quantity shall:

(a) Utilize the lowest of logic established by Section 2 of this administrative regulation; and

(b) Include payment of only one (1) professional dispensing fee, which shall be paid at the time of the completion fill.

(3) Maintenance drugs. The department shall not reimburse for a refill of a maintenance drug prior to the end of the dispensing period established by 907 KAR 23:010 unless the department determines that it is in the best interest of the recipient.

(4) For a nursing facility resident meeting Medicaid nursing facility level of care criteria, and in accordance with 201 KAR 2:190 and 902 KAR 55:065, an unused drug paid for by Medicaid shall be returned to the originating pharmacy and the department shall be credited for the drug ingredient cost.

(5) For a Medicaid recipient participating in a hospice program, payment for a drug shall be in accordance with 907 KAR 1:340.

(6) 340B Pharmacy Transactions.

(a) A pharmacy dispensing drugs purchased through the 340B Program pursuant to a 340B eligible prescription from a covered entity shall bill the department no more than the actual 340B acquisition cost, plus the professional dispensing fee.

(b) For a 340B purchased drug dispensed by a pharmacy, the lowest of logic shall include the 340B ceiling price.

(c) A drug dispensed by a 340B contract pharmacy shall not be eligible as a 340B transaction and shall be reimbursed in accordance with the lowest of logic as required by Section 2 of this administrative regulation plus the professional dispensing fee.

(d) Reimbursement to a 340B in-house or contract pharmacy dispensing a 340B eligible prescription for the managed care population shall not include the 340B ceiling price in the lowest of logic.

(7) Physician administered drugs (PAD).

(a) Federal rebate required. Only covered PAD products that are federally rebateable pursuant to a manufacturer rebate agreement shall be reimbursed.

(b) Non-340B purchased PAD. Reimbursement for drug cost for a drug administered by a physician or the physician's authorized agent in an office or outpatient clinic setting, not purchased through the 340B Program, and submitted for reimbursement as a medical benefit shall be reimbursed only for the drug cost by the lowest of logic required by Section 2 of this administrative regulation, which shall include the average sales price (ASP) plus six (6) percent. A professional dispensing fee shall not be paid for PAD.

(c) 340B purchased PAD. For a drug purchased through the 340B Program and administered by a physician or the physician's authorized agent in an office or outpatient clinic setting, and submitted for reimbursement as a medical benefit, the lowest of logic required by Section 2 of this administrative regulation shall include the 340B ceiling price. The covered entity shall bill no more than the actual 340B acquisition cost. A professional dispensing fee shall not be paid for PAD.

~~[(8) Non-340B hemophilia products. Clotting factors acquired outside of the 340B Program shall be reimbursed by the lowest of logic required by Section 2 of this administrative~~

~~regulation, which shall include the average sales price (ASP) plus six (6) percent. The professional dispensing fee established by Section 3 of this administrative regulation shall also be paid.]~~

Section 5. The maximum allowable cost, or MAC, shall be determined by taking into account each drug's cost, rebate status (non-rebateable or rebateable) in accordance with 42 U.S.C. 1396r-8(a), marketplace status (obsolete, terminated, or regional availability), equivalency rating (A-rated), and relative comparable pricing. Other factors considered shall include clinical indications of drug substitution, utilization, and availability in the marketplace. (1) Drug pricing resources used to compare estimated acquisition costs for multiple-source drugs shall include comprehensive data files maintained by a vendor under contract to the department, such as:

(a) NADAC as published by CMS;

(b) WAC, manufacturer's price list, or other nationally recognized sources;

(c) The Average Manufacturers Price for 5i Drugs as reported by CMS;

(d) ASP as published by CMS;

(e) Nationally recognized drug file vendors approved for use at a federal level and that have been approved by the department;

(f) Pharmacy providers; or

(g) Wholesalers.

(2) The department shall maintain a current listing of drugs and their corresponding MAC prices accessible through the department's pharmacy webpage.

(3) The process for a pharmacy provider to appeal a MAC price for a drug shall be as established in this subsection.

(a) The pharmacy provider shall email or fax a completed Kentucky Medicaid MAC Price

1 Research Request Form to Kentucky's authorized agent in accordance with the instructions on  
2 the form.

3 (b) An appeal of a MAC price for a drug shall be investigated and resolved within three (3)  
4 business days.

5 (c) If available, the provider shall be supplied with the name of one (1) or more manufacturers  
6 who have a price comparable to the MAC price.

7 (d) The MAC price and effective date of that price shall be adjusted accordingly, retroactive  
8 to the date of service for the claim in question, if:

9 1. It is determined that a manufacturer does not exist in the price range referenced in para-  
10 graph (c) of this subsection; or

11 2. The provider is able to document that despite reasonable efforts to obtain access, he or she  
12 does not have access to the one (1) or more manufacturers supplied to the provider.

13 (e) If an adjusted MAC price becomes effective, the provider shall be informed that the claim  
14 may be rebilled for the price adjustment.

15 Section 6. Federal Approval and Federal Financial Participation. The department's reim-  
16 bursement for services pursuant to this administrative regulation shall be contingent upon:

17 (1) Receipt of federal financial participation for the reimbursement; and

18 (2) Centers for Medicare and Medicaid Services' approval for the reimbursement.

19 Section 7. Incorporation by Reference. (1) "Kentucky Medicaid MAC Price Research Request  
20 Form", 2012, is incorporated by reference.

21 (2) This material may be inspected, copied, or obtained, subject to applicable copyright law,  
22 at:

23 (a) The Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky, Mon-



- 1 day through Friday, 8:00 a.m. to 4:30 p.m.; or
- 2 (b) Online at the department's Web site at
- 3 <https://chfs.ky.gov/agencies/dms/dpo/ppb/Pages/default.aspx> [<http://www.chfs.ky.gov/dms/incorp>
- 4 [orated.htm](http://www.chfs.ky.gov/dms/incorporated.htm)].

907 KAR 23:010E

REVIEWED:

9/13/2021

Date

DocuSigned by:

*Lisa Lee*

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Lisa D. Lee, Commissioner  
Department for Medicaid Services

APPROVED:

9/14/2021

Date

DocuSigned by:

*Eric Friedlander*

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Eric Friedlander, Secretary  
Cabinet for Health and Family Services

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation Number: 907 KAR 23:010E

Agency Contact Persons: Jonathan Scott, (502) 564-4321, ext. 2015, jonathant.scott@ky.gov;  
and Krista Quarles, (502) 564-6746, CHFSRegs@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the Department for Medicaid Services' (DMS's) reimbursement provisions and requirements regarding outpatient drugs dispensed or administered to all Medicaid recipients.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish DMS's reimbursement provisions and requirements regarding all outpatient drugs dispensed or administered to Medicaid recipients.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing DMS's reimbursement provisions and requirements regarding outpatient drugs dispensed or administered to all Medicaid recipients.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the authorizing statutes by establishing DMS's reimbursement provisions and requirements regarding outpatient drugs dispensed or administered to all Medicaid recipients.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment implements 2020's SB 50 and the department's awarded request for proposals as required by that legislation. The administrative regulation is amended to clarify when the professional dispensing fee can be assessed, clarify clotting factor reimbursement, and establish professional dispensing fees for compounded drugs. Finally, the regulation is amended to remove cost-sharing and comply with Senate Bill 55's removal of all co-pays.

The Emergency Amended After Comments version of the administrative regulation is amended to clarify that a professional dispensing fee is not needed when a usual and customary charge is paid for an outpatient pharmacy prescription. In addition, the regulation is amended to clarify that both in-house and contract 340B pharmacy reimbursement do not include the 340B ceiling price in the lowest of logic methodology. Finally, clotting factor reimbursement is now addressed in Section 2 of the administrative regulation, as a result, Section 4(8) became redundant and is being deleted.

(b) The necessity of the amendment to this administrative regulation: This administrative regulation is needed to implement 2020's SB 50 and the department's awarded request for proposals as required by that legislation.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment allows for the implementation of a single-state PBM as required by KRS 205.5512-.5520.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will allow for 2020's SB 50 to be fully implemented.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: All participating pharmacy providers dispensing covered drugs (approximately 1,500) and all participating medical providers administering covered drugs (approximately 46,000) will be affected by the administrative regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: In order to be reimbursed by the DMS, participating providers will have to submit pharmacy or medical claims for covered outpatient drugs in accordance with this administrative regulation and applicable billing rules.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional costs experienced by affected providers.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Applicable providers will benefit by receiving a true drug ingredient cost based reimbursement along with a professional dispensing fee from DMS for dispensing covered outpatient drugs to all Medicaid recipients.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: DMS estimates that moving to a single PBM model for all Medicaid recipients will be cost-neutral. DMS will continue to assess costs and provide updates via the required reporting functions of 2021's SB 192 and KRS 205.5510 to 205.5520.

(b) On a continuing basis: DMS estimates that moving to a single PBM model for all Medicaid recipients will be cost-neutral. DMS will continue to assess costs and provide updates via the required reporting functions of 2021's SB 192 and KRS 205.5510 to 205.5520.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Sources of funding to be used for the implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX and Title XXI of the Social Security Act, and state matching funds of general and agency appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: At this time, DMS does not assess that an increase in fees or funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9) Tiering: Is tiering applied? Tiering was not appropriate in this administrative regulation because the administration regulation applies equally to all those individuals or entities regulated by it.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation Number: 907 KAR 23:020E

Agency Contact Persons: Jonathan Scott, (502) 564-4321, ext. 2015, jonathant.scott@ky.gov;  
and Krista Quarles, (502) 564-6746, CHFSRegs@ky.gov

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? DMS will be affected by this administrative regulation.
2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560, 205.561(2), 205.6316(4), 42 U.S.C. 1396a(a)(30), 42 U.S.C. 1396r-8
3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
  - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate revenue for state or local government.
  - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate revenue for state or local government.
  - (c) How much will it cost to administer this program for the first year? DMS estimates that moving to a single PBM model for all Medicaid recipients will be cost-neutral. DMS will continue to assess costs and provide updates via the required reporting functions of 2021's SB 192 and KRS 205.5510 to 205.5520.
  - (d) How much will it cost to administer this program for subsequent years? DMS estimates that moving to a single PBM model for all Medicaid recipients will be cost-neutral. DMS will continue to assess costs and provide updates via the required reporting functions of 2021's SB 192 and KRS 205.5510 to 205.5520.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): \_\_\_\_\_

Expenditures (+/-): \_\_\_\_\_

Other Explanation: \_\_\_\_\_

## FEDERAL MANDATE ANALYSIS COMPARISON

Administrative Regulation Number: 907 KAR 23:020E

Agency Contact Persons: Jonathan Scott, (502) 564-4321, ext. 2015, jonathant.scott@ky.gov;  
and Krista Quarles, (502) 564-6746, CHFSRegs@ky.gov

1. Federal statute or regulation constituting the federal mandate. 42 C.F.R. Part 447.
2. State compliance standards. KRS 205.520(3) states: "Further, it is the policy of the Commonwealth to take advantage of all federal funds that may be available for medical assistance. To qualify for federal funds the secretary for health and family services may by regulation comply with any requirement that may be imposed or opportunity that may be presented by federal law. Nothing in KRS 205.510 to 205.630 is intended to limit the secretary's power in this respect."
3. Minimum or uniform standards contained in the federal mandate. 42 U.S.C. 1396a(a)(10)(B) requires the Medicaid Program to ensure that services are available to Medicaid recipients in the same amount, duration, and scope as available to other individuals (non-Medicaid). Revising reimbursement methodology for outpatient drugs dispensed or administered to Medicaid recipients shall not change compliance standards.
4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? The administrative regulation does not impose stricter or different responsibilities than the federal requirements.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The administrative regulation does not impose stricter or different responsibilities than the federal requirements.

STATEMENT OF CONSIDERATION RELATING TO  
907 KAR 23:020E

CABINET FOR HEALTH AND FAMILY SERVICES  
Department for Medicaid Services  
Division of Policy and Operations

Amended After Comments

I. A public hearing on 907 KAR 23:020 was held on August 23, 2021 at 9:00 a.m., all participants were present via Zoom. In addition, written comments were received during the public comment period.

II. The following individuals submitted comments during the public comment period:

<b><u>Name and Title</u></b>	<b><u>Agency/Organization/Entity/Other</u></b>
Chris Harlow, Pharm.D., Director of Pharmacy Services	Cordant Health Solutions and St. Matthews Community & Specialty Pharmacy
John Inman, Chief Policy and External Affairs Officer	Kentucky Primary Care Association
Susan Sommer, CEO	Cordant Health Solutions
Rebecca Randall, Senior Director, Operations	WellCare Health Plans of Kentucky
Jonathan Scott, Regulatory and Legislative Advisor	Department for Medicaid Services, Commissioner's Office

III. The following individuals from the promulgating agency responded to comments received regarding 907 KAR 3:060.

<b><u>Name and Title</u></b>	<b><u>Agency/Organization/Entity/Other</u></b>
Lisa Lee, Commissioner	Department for Medicaid Services, Commissioner's Office
Veronica Cecil, Senior Deputy Commissioner	Department for Medicaid Services, Commissioner's Office
Fatima Ali, Interim Pharmacy Director	Department for Medicaid Services, Division of Policy and Operations



Noah Dixon, Pharmacy Intern	Department for Medicaid Services, Division of Policy and Operations
Jonathan Scott, Regulatory and Legislative Advisor	Department for Medicaid Services, Commissioner's Office

#### IV. SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Limitation of number of dispensing fees per month

(a) Comment: Chris Harlow, Pharm.D., Director of Pharmacy Services, Cordant Health Solutions and St. Matthews Community & Specialty Pharmacy, submitted comments pointing out that the implementation of the administrative regulation limits pharmacies to only one (1) dispensing fee per month. 95% of the St. Matthews pharmacy population is individuals that are MAT patients, and 77% of the prescriptions for buprenorphine/naloxone are for less than 23 days. Dr. Harlow further points out that Cordant and its other Kentucky affiliates are one of the largest pharmacies serving medication assisted treatment (MAT) patients with substance use disorder (SUD) having served over 5,300 patients in the previous year. Due to the reduction in fees, the program will likely be discontinued. Dr. Harlow suggest that an exception to the \$10.64 dispensing fee per pharmacy provider per recipient per drug per month should be provided in order to compensate pharmacy providers for additional dispenses as warranted by the applicable standards of care.

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that the proposed requirement will cause pharmacy providers to lose reimbursement on prescriptions for which the applicable standard of medical care requires additional dispenses per month or during an applicable time period. A specific example of a 7-14 day interval for certain SUD MAT drugs is cited by the commenter. This commenter points out that Cordant Health Solutions has served more than 8,000 patients diagnosed with SUD and worked with over 160 MAT providers in the previous year.

(b) Response: DMS has evaluated the difference in dispensing fee both before and after the implementation of the single-state PBM and determined that there has not been a reduction in reimbursement. DMS furthermore believes that most providers are receiving increased reimbursement. The department will not be amending the administrative regulation in response to the comment.

(2) Subject: Specialty pharmacy dispensing fee

(a) Comment: Chris Harlow, Pharm.D., Director of Pharmacy Services, Cordant Health Solutions and St. Matthews Community & Specialty Pharmacy, submitted comments pointing out that the department did not institute a specialty pharmacy dispensing fee with the implementation of the single managed care organization (MCO) pharmacy benefit manager (PBM). He further points out that a specialty pharmacy dispensing fee recommendation was proposed by the Pharmacy Technical Advisory Committee (PTAC) and was the mean specialty drug cost for dispensing as determined by the 2020 Cost-of-Dispensing Study. This suggested specialty pharmacy dispensing fee recommendation was \$73.58.

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments highlighting the discussion at the October 2020 meeting of the PTAC and arguing that the dispensing fee of \$10.64 per pharmacy provider per recipient is inadequate to compensate specialty pharmacy providers. A suggestion of a \$75-\$100 specialty pharmacy dispensing fee is made as well as a later request to utilize the \$73.58 dispensing fee.

(b) Response: The department has evaluated the recommendation to establish a higher specialty pharmacy dispensing fee, and has determined that it was unnecessary. The department will continue to evaluate specialty pharmacy costs and specialty pharmacy dispensing fees utilized in other states. However, no immediate higher dispensing fee will be implemented. The department will not be amending the administrative regulation in response to the comment.

(3) Subject: Reduction of 65% in reimbursement for generic buprenorphine/naloxone

(a) Comment: Chris Harlow, Pharm.D., Director of Pharmacy Services, Cordant Health Solutions and St. Matthews Community & Specialty Pharmacy, submitted comments indicating that the change in reimbursement methodology from June to July resulted in a 65% reimbursement for generic buprenorphine/naloxone.

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments pointing out that the 65% reduction in reimbursement extends to all Cordant pharmacies in Kentucky, and that the emergency regulation directly impacts Cordant's ability to continue to provide SUD prescriptions to Kentuckians.

(b) Response: The reimbursement methodology currently utilized by the department is not substantially different than prior to July 1, 2021. The pharmacies continue to have all existing appeal options to request a reevaluation of a reimbursed cost. The department would encourage the pharmacies to exhaust all appeal options, as those are unchanged after the transition to the single-state PBM. The department will not be amending the administrative regulation in response to the comment.

(4) Subject: Vivitrol dispensing and administration expenses

(a) Comment: Chris Harlow, Pharm.D., Director of Pharmacy Services, Cordant Health Solutions and St. Matthews Community & Specialty Pharmacy, submitted comments describing how a patient would initiate a prescription for Vivitrol via a St. Matthews' pharmacy Board approved protocol. This process involves a 30-45 minute visit with a pharmacist. During this protocol a urine drug screen will be completed, a withdrawal assessment will be conducted, a test-dose of a naltrexone tablet may be conducted, and then the medication will be administered. Pharmacists are not enrolled by Medicaid, and therefore cannot receive reimbursement for these individual services. For this service, pharmacists "depend on a fair and reasonable dispensing fee".

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments indicating that the \$10.64 dispensing fee was inadequate to reimburse Cordant for Vivitrol dispensing and administration due to patient monitoring and management, medication use training, health care treatment assessments, and supply chain management functions including special storage, handling, and shipment services.

(b) Response: The department is not prepared to enroll pharmacists as providers at this time. No change in reimbursement methodology has occurred as a result of this transition to a single-state PBM. The department has determined that this reimbursement and separate dispensing fee is appropriate for the costs of dispensing drugs. The department plans to continue evaluating the program at periodic intervals to consider additional dispensing fee needs. If additional health ser-

vices are being provided within the pharmacy setting that are not otherwise reimbursable by the Medicaid program, it may be appropriate for the prescribing provider to provide additional reimbursement to the pharmacy when those services are provided. Currently, those services do not appear to be covered by the Medicaid program and would be appropriately addressed between clinician and pharmacist. The department will not be amending the administrative regulation in response to the comment.

(5) Subject: Sublocade care coordination

(a) Comment: Chris Harlow, Pharm.D., Director of Pharmacy Services, Cordant Health Solutions and St. Matthews Community & Specialty Pharmacy, submitted comments discussing how the pharmacy works to fulfill Sublocade orders. This involves a drug utilization review involving a review of a patient chart, a benefits investigation, a prescription drug monitoring program search, mandatory FDA REMS program requirements, and cold-chain shipping directly to the prescribing provider.

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments indicating that the \$10.64 dispensing fee was inadequate to reimburse Cordant for Sublocade dispensing and administration due to patient monitoring and management, medication use training, health care treatment assessments, and supply chain management functions including special storage, handling, and shipment services.

(b) Response: The department is not prepared to enroll pharmacists as providers at this time. No change in reimbursement methodology has occurred as a result of this transition to a single-state PBM. The department has determined that this reimbursement and separate dispensing fee is appropriate for the costs of dispensing drugs. The department plans to continue evaluating the program at periodic intervals to consider additional dispensing fee needs. If additional health services are being provided within the pharmacy setting that are not otherwise reimbursable by the Medicaid program, it may be appropriate for the prescribing provider to provide additional reimbursement to the pharmacy when those services are provided. Currently, those services do not appear to be covered by the Medicaid program and would be appropriately addressed between clinician and pharmacist. The department will not be amending the administrative regulation in response to the comment.

(6) Subject: Shipping costs not included in dispensing fees

(a) Comment: Chris Harlow, Pharm.D., Director of Pharmacy Services, Cordant Health Solutions and St. Matthews Community & Specialty Pharmacy, submitted comments pointing out that for some medications if the medication is not administered at the pharmacy by a pharmacist, then the pharmacy must ship the medication to the provider for administration. This additional cost is not covered by the current \$10.64 dispensing fee.

(b) Response: It is the department's position that the dispensing fee is intended to cover all costs of dispensing. The department will not be amending the administrative regulation in response to the comment.

(7) Subject: Mandatory accreditation requirements by certain drug manufacturers

(a) Comment: Chris Harlow, Pharm.D., Director of Pharmacy Services, Cordant Health Solutions and St. Matthews Community & Specialty Pharmacy, submitted comments indicating that certain drug manufacturers are requiring specific mandatory accreditations in order to get access to certain specialty pharmacy medications.

(b) Response: A pharmacy must meet any requirements of mandatory accreditations that are imposed on it by outside entities. The department is not requiring additional mandatory accreditations of pharmacies. The department will not be amending the administrative regulation in response to the comment.

(8) Subject: Clarification of reimbursement methodologies

(a) Comment: John Inman, Chief Policy and External Affairs Officer, Kentucky Primary Care Association submitted comments contending that the actual reimbursement logic and price indices should be placed in the administrative regulation. Including the specific indices would be used when a dispute arises as to reimbursement for a drug ingredient cost paid on a pharmacy benefit claim.

(b) Response: The actual reimbursement logic is set forth in Section 2 of the administrative regulation. The department prefers to preserve flexibility between indices at this time. DMS would request additional proposed language for consideration within the ordinary administrative regulation filed with this emergency administrative regulation. The department will not be amending the administrative regulation in response to the comment.

(9) Subject: Inclusion of 340B in-house pharmacies within administrative regulation

(a) Comment: John Inman, Chief Policy and External Affairs Officer, Kentucky Primary Care Association submitted comments requesting that the administrative regulation be clarified to acknowledge in-house and contract pharmacies associated with a 340B Covered Entity.

(b) Response: The department intends to continue clarifying this issue and promulgate a specific regulation relating to the 340B process. However, the department will amend the administrative regulation in response to the comment as follows:

Reimbursement to a 340B in-house or contract pharmacy dispensing a 340B eligible prescription for the managed care population shall not include the 340B ceiling price in the lowest of logic.

(10) Subject: Physician Administered Drugs (PAD) reimbursement

(a) Comment: John Inman, Chief Policy and External Affairs Officer, Kentucky Primary Care Association submitted comments requesting that a separate section addressing PAD reimbursement for the managed care population be included. The comment further requests that 340B purchased drugs administered to covered entity patients not be included in the lowest of logic pursuant to SB 50.

(b) Response: It is the department's position that PADs were not impacted by SB 50. As a result, the existing PAD reimbursement structure will be maintained. The department will not be amending the administrative regulation in response to the comment.

(11) Subject: Specialty pharmacies and the applicable standard of care

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that specialty pharmacy providers are subject to the standard of care applied by the Kentucky Medical Board of Licensure to patients taking buprenorphine. This comment also discusses the practice of Kentucky prescribers in which they issue MAT prescriptions on a one-to-two week medication protocol for six (6) months or longer. The argument is that a specialty pharmacy would be subject to ongoing losses as a result of a once per every 23 days dispensing fee.

(b) Response: DMS has evaluated the difference in dispensing fee both before and after the implementation of the single-state PBM and determined that there has not been a reduction in reimbursement. DMS furthermore believes that most providers are receiving increased reimbursement. The department will not be amending the administrative regulation in response to the comment.

(12) Subject: Kentucky Opioid Response Effort (KORE) and DMS pharmacy

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments requesting that the DMS pharmacy regulation align with the goals established in the CHFS' KORE program goals.

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments in an Appendix document suggesting that DMS is bound by the Commonwealth's KORE program goals.

(b) Response: The department is not bound by that separate agency's recommendations about the opioid epidemic in determining reimbursement methodologies for pharmacy. The department will not be amending the administrative regulation in response to the comment.

(13) Subject: Express requirement of the PBM contract to be subject to DMS administrative regulations.

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments requesting that the administrative regulation expressly state that the terms of the PBM contract are subject to "rules and regulations" promulgated by CHFS.

(b) Response: The terms of the PBM contract are subject to the administrative regulations promulgated by CHFS, specifically the Department for Medicaid Services. The department will not be amending the administrative regulation in response to the comment.

(14) Subject: Prohibition of reimbursement of a refill of a maintenance medication

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that the emergency regulation's prohibition of reimbursement for a refill of a maintenance medication prior to the end of the dispensing period, unless this dispensing is in the best interest of the patient, reduces the Medicaid benefits of recipients in the Commonwealth. The commenter further argues that this requirement will cause pharmacy providers to lose reimbursement dollars when the standard of care requires refills of a maintenance medication. The commenter argues that the terms "maintenance medication" and "best interest of the recipient" should be defined, and that using a "best interest of the recipient" requirement allows for CHFS to make clinical and medical decision making that should instead be within the purview of the recipient's treating medical and pharmacy providers.

(b) Response: The department's dispensing fees established pursuant to this administrative regulation should not impact the clinical methodology by which a clinician and a pharmacy meet their professional and statutory obligations in treating a patient's condition. Furthermore, the department determined that the total dispensing fee received by a pharmacy, even in the case of multiple fills over twenty-three (23) days, is greater than the amount received prior to the implementation of the single-state PBM. In addition, a pharmacy would receive a drug cost reimbursement for each fill during the twenty-three (23) day period. The department will not be amending the administrative regulation in response to the comment.

(15) Subject: No grounds for an emergency administrative regulation

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that the Medicaid state plan must be updated in order to implement the MCO single-state PBM, and that DMS has not submitted a state plan amendment to implement it.

(b) Response: A state plan amendment is not needed to implement the single state MCO PBM. The department will not be amending the administrative regulation in response to the comment.

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that the Medicaid state plan prohibits implementation of the emergency administrative regulation because it will result in an inadequate network of providers.

(b) Response: The Medicaid state plan does not prohibit the implementation of the emergency administrative regulation. The department will not be amending the administrative regulation in response to the comment.

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that there are no grounds for an emergency administrative regulation because there is no imminent risk to public health, safety, welfare, or the environment.

(b) Response: The department contends that ensuring that there is an adequate network of pharmacy providers is an issue of public health and welfare for the Commonwealth. Ensuring existing independent pharmacies remain viable preserves the health and welfare of Medicaid members. The department will not be amending the administrative regulation in response to the comment.

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments suggesting that the department has “attempted to manufacture an emergency by entering into a contract with MedImpact”. The commenter further states that the department “spent the year between May 2020 and April 2021 considering possible dispensing fees until ‘final decisions relating to dispensing fees were made [in] April of 2021.’” The commenter further states that any potential decisions that the department was making should have been subject to the Kentucky Administrative Procedure Act’s notice and comment requirements during that period.

(b) Response: The department would redirect the commenter’s attention to KRS 13A.190(1). That statute does not establish a checklist in which every element must be met in order to justify an emergency regulation. Rather, an emergency administrative regulation can be justified whenever any of the listed criteria are met. The department is specifically pointing to three (3) of those listed criteria in justifying the existence of an emergency.

Furthermore, the department is operating under the requirements of Senate Bill 50 from the 2020 Regular Session that required the department to establish a single state pharmacy benefit manager by December 31, 2020. Under Kentucky law, state agencies are bound by the requirements of KRS Chapter 45A when procuring goods and services. The department succeeded in meeting the requirements of SB 50 by having a procured single-state PBM contract in place by December 31, 2020. The terms of the procured contract – as required by SB 50 – were to implement the single-state MCO PBM by July 1, 2021. The department will not be amending the administrative regulation in response to the comment.

(16) Subject: DMS and the “Kentucky Administrative Procedure Act”

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments arguing that CHFS is required to conduct “research, study, and fact-gathering processes” prior to implementing an administrative regulation. Furthermore, the commenter argues that DMS is required to prepare regulatory impact analyses, tiering statements, fiscal notes, and federal mandate analysis documents for every provider letter issued by the department.

(b) Response: The department filed administrative regulations in compliance with KRS Chapter 13A. The department had significant stakeholder engagement throughout implementation of the single State MCO PBM. The department will not be amending the administrative regulation in response to the comment.

(17) Subject: Failure to submit documentary evidence

(a) Comment: Susan Sommer, CEO, Cordant Health Solutions, submitted comments stating that DMS did not submit any documentary evidence when filing the administrative regulation.

(b) Response: The department submitted documentary evidence consistent with the requirements of Senate Bill 2 when filing the administrative regulation. The department will not be amending the administrative regulation in response to the comment.

(18) Subject: Clotting Factor Reimbursement

(a) Comment: Rebecca Randall, Senior Director, Operations, WellCare Health Plans of Kentucky, submitted comments requesting that DMS clarify clotting factors when they are dispensed by a pharmacy or when it is administered in a physician’s office. The request is that the administrative regulation be amended to specify that the Section 2(3) reimbursement only applies when a member obtains clotting factor from an outpatient pharmacy, and that if clotting factor is administered in a physician’s office that the reimbursement shall be as established in Section 4(7) of the administrative regulation.

(b) Response: The administrative regulation correctly reflects the reimbursement based on whether or not the drug is obtained via a pharmacy or a physician’s office. Clotting factor obtained from an outpatient pharmacy should be reimbursed pursuant to Section 2(3) of the administrative regulation. Clotting factor administered in a physician’s office should be reimbursed pursuant to Section 4(7)(b). For clarification purposes, the department will amend the administrative regulation to remove Section 4(8).

(19) Subject: Usual and Customary Charge

(a) Comment: Noah Dixon, Pharmacy Intern, Department for Medicaid Services submitted comments indicating that the phrase “plus the professional dispensing fee” should not have been included when referring to a pharmacy’s usual and customary charge. It is standard within this industry that no professional dispensing fee is charged in these cases. In addition, the department’s federal financial approval does not include that a professional dispensing fee is available when a pharmacy requests reimbursement based on a usual and customary charge.

(b) Response: The department agrees with this comment and will delete the term from the regulation where it appears in conjunction with “usual and customary charge”.

V. SUMMARY OF STATEMENT OF CONSIDERATION  
AND  
ACTION TAKEN BY PROMULGATING ADMINISTRATIVE BODY

The Department for Medicaid Services (DMS) has considered the comments received regarding 907 KAR 23:020E. This administrative regulation is being amended after comments. DMS is amending the administrative regulations as follows:

Section 2(2)(e)

Page 5

Line 6

Delete “, plus the professional dispensing fee”.

Section 4(6)(d)

Page 7

Line 4

After “to a 340B” insert “in-house or”.

Section 4(8)

Page 7

Lines 20-23.

Delete lines 20-23 in their entirety.